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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:

Terry L. Gilton

Serial No.: 09/443,070

Filed: November 18, 1999

For: SEPARATION APPARATUS INCLUDING POROUS SILICON COLUMN

Examiner: G. Gabel

Group Art Unit: 1641

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BRIEF ON APPEAL

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Attention: Board of Patent Appeals and Interferences

Sirs:

This brief is submitted in TRIPLICATE pursuant to 37 C.F.R.§ 1.192(a) and in the format required by 37 C.F.R. § 1.192(c) and with the fee required by 37 C.F.R. § 1.17(c):

(1) REAL PARTY IN INTEREST

U.S. Serial No. 09/443,070, the patent application at issue in the above-referenced appeal, has been assigned to Micron Technology, Inc. ("Assignee"). The assignment has been recorded with the United States Patent & Trademark Office ("Office") at Reel No. 9551, Frame No. 0837. Accordingly, Micron Technology, Inc. is the real party in interest to the referenced appeal.

(2) RELATED APPEALS AND INTERFERENCES

Neither Appellant, Appellant's representative, nor Assignee is aware of any pending appeal or interference which would directly affect, be directly affected by, or have any bearing on the Board's decision in the present pending appeal.

(3) STATUS OF CLAIMS

Claims 1, 2, 8, and 12-31 are currently pending in the above-referenced patent application. Claims 1, 2, 8, and 12-31 stand rejected.

Claims 3-7 and 9-11 were previously cancelled without prejudice or disclaimer.

No claims have been allowed.

The rejections of claims 1, 2, 8, and 12-31 are being appealed.

(4) STATUS OF AMENDMENTS

Claims 1-29 were initially filed in the application. Claims 3-7 and 9-11 were cancelled, without prejudice, in response to the Office Action mailed on May 24, 2000.

The last amendment to the claims of the referenced patent application that was entered by the Office was filed by Appellant on February 8, 2001.

Claims 1, 2, 8, and 12-31 were rejected in a final Office Action mailed on April 24, 2001.

On May 30, 2001, Appellant filed an Amendment Under 37 C.F.R. § 1.116 in response to the Final Office Action, wherein claims 1, 2, 8, and 12-31 were discussed in an effort to point out the patentability of the subject matter recited in each of these claims.

In an Advisory Action mailed on June 26, 2001, the rejections of claims 1, 2, 8, and 12-31 were renewed. The first sheet of the Advisory Action incorrectly states that claims 1, 2, 8, and 13-31 are rejected. However, the remainder of the Advisory Action correctly states that claims 1, 2, 8, and 12-31 are rejected. The Advisory Action states that Appellant's Response does not overcome the rejections.

A first Notice of Appeal in the above-referenced application was mailed on July 2, 2001, and an appeal brief was filed on August 31, 2001.

The Examiner reopened prosecution of the above-referenced application by issuing an Office Action on December 5, 2001. Claims 1, 2, 8, and 12-31 were again rejected in the Office Action dated December 5, 2001.

In response to the Office Action dated December 5, 2001, which response was filed on March 5, 2002, an effort was again made to point out the patentable features of claims 1, 2, 8, and 12-31.

Each of these claims was again rejected in a second final Office Action, mailed on May 16, 2002.

In a response dated July 22, 2002, yet another effort was made to explain the patentable features of claims 1, 2, 8, and 12-31.

Nevertheless, in an Advisory Action dated August 8, 2002, the rejections of claims 1, 2, 8, and 12-31 were maintained.

Accordingly, a second Notice of Appeal was filed in the above-referenced application on August 12, 2002.

(5) SUMMARY OF THE INVENTION

The invention disclosed in the above-referenced application and recited in the claims thereof includes a method of substantially isolating a constituent of a sample. Page 20, lines 1-3. In the claimed method, the sample is dispersed in a mobile phase and applied to the first end of a porous capillary column 14. Page 19, lines 17-27. The porous capillary column 14 is formed on a substrate 12, which is formed from silicon or other materials that may be treated to form porous regions therein. Page 10, lines 21-22; page 11, lines 1-3. Each substrate 12 may include multiple porous capillary columns 14 which are formed by patterning the substrate 12. Page 16, lines 3-7.

Each porous capillary column 14 further includes a matrix 16 that is made of porous silicon. Page 10, lines 22-23; page 11, lines 3-4. A capture substrate or stationary phase 117 is bound to the matrix 16 at a reaction region 120. Page 15, lines 26-30. The capture substrate is an antibody, antigen, any other specific-binding molecule, or a material that separates the constituent from the sample based on the capture substrate's affinity for the constituent. Page 15, lines 21-23.

After being applied to the column, the sample is drawn through the porous capillary column 14 by movement of the mobile phase. Page 20, lines 7-11. The sample may migrate by capillary action or with assistance from a migration facilitator 24, such as a pump, vacuum source, or electrical current generator. Page 13, line 18, to page 15, line 9. As the sample migrates through the porous capillary column 14, the constituents contained in the sample come into contact with the capture substrate 117. Page 21, lines 26-27. If one of the constituents has affinity for the capture substrate 117, the constituent will bind to the capture substrate 117, thereby isolating that constituent from the remainder of the sample. Page 21, line 27, to page 22, line 1. The constituents that do not have affinity for the capture substrate 117 continue to migrate through the porous capillary column 14. Page 21, line 27, to page 22, line 1.

A detector 22 or 122 detects the presence or absence of the constituent bound to the capture substrate 117. Page 22, lines 1-5. The detector 22 is located at the end of the capillary column or proximate to a reaction region 20 of each capillary column 14. Page 12, lines 16-17.

(6) ISSUE

Whether United States Patent 5,571,410, issued to Swedberg et al. (hereinafter "Swedberg"), anticipates claims 1, 2, 8, and 12-31 of the above-referenced application under 35 U.S.C. § 102(b).

(7) GROUPING OF CLAIMS

Claims 1, 2, 8, and 12-31 are commonly rejected as anticipated by Swedberg. Claims 1 and 18 stand and fall separately. Accordingly, claims 1, 2, 8, 12-17, and 30 are grouped separately from claims 18-29 and 31 since claims 1, 2, 8, 12-17, and 30 are directed to a method which includes applying a sample to a *porous* capillary column *formed in* a substrate, while claims 18-29 and 31 are directed to a method which includes applying a sample to a capillary column which is formed in a substrate and includes a matrix.

Group 1: Claims 1, 2, 8, 12-17, and 30:

Claims 1, 2, 8, 12-17, and 30 are grouped together. Claim 1 appears to be the most generic claim of Group 1. For purposes of this appeal, claims 2, 8, and 12-17, and 30 stand and fall with claim 1.

Group 2: Claims 18-29 and 31:

Claims 18-29 and 31 are grouped together. Claim 18 appears to be the most generic claim of Group 2. For purposes of this appeal, claims 19-29 and 31 stand and fall with claim 18.

(8) ARGUMENT

Rejection under 35 U.S.C. § 102(b)

Claims 1, 2, 8, and 12-31 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Swedberg.

35 U.S.C. § 102(b) provides that:

> A person shall be entitled to a patent unless–
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

A claim is anticipated only if each and every element thereof, as set forth in the claim, is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Brothers v. Union Oil Co. of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989).

Swedberg

Swedberg describes separation apparatus, or "total analysis systems," that include substrates that may be formed from the following materials: polycarbonates; polyesters, including poly(ethylene terephthalate) and poly(butylene terephthalate); polyamides, (such as nylons); polyethers, including polyformaldehyde and poly(phenylene sulfide); polyimides, such as KAPTON® and UPILEX®; polyolefin compounds, including ABS polymers, Kel-F copolymers, poly(methyl methacrylate), poly(styrene-butadiene) copolymers,

poly(tetrafluoroethylene), poly(ethylenevinyl acetate) copolymers, poly(N-vinylcarbazole) and polystyrene. Swedberg, col. 21, line 49 through col. 22, line 4. Swedberg also describes that the substrate of a separation apparatus may be formed from ceramics (including aluminum oxides and the like) and composite substrates, such as laminates. Swedberg, col. 7, lines 56-64.

In some of the embodiments of separation apparatus that are described in Swedberg, the miniaturized columns that have been formed in the substrate are filled with a porous medium, which is made of particles, sheets or membranes. Swedberg, col. 27, lines 33-35. The porous medium is biocompatible and may be made from such materials as nylon, cellulose, polymethylmethacrylate, polyacrylamide, agarose, or the like. Swedberg, col. 27, lines 37-40.

Claims 1, 2, 8, 12-17, and 30

Independent claim 1, as well as claims 2, 8, 12-17, and 30 which depend therefrom, are directed to a method which includes applying a sample to a porous capillary column *formed in* a substrate, with a matrix of the porous capillary column and the nonporous substrate comprising the same material.

Swedberg lacks any express or inherent description of a method which includes applying a sample to a porous capillary column which is *formed in* a nonporous substrate. Instead, the description provided by Swedberg is limited to use of a device which includes a column that is formed in a nonporous substrate, then *filled with* a separately formed porous medium. Swedberg, col. 27, lines 33-35. Accordingly, the porous portion of the separation device which is described in Swedberg is not *formed in* the nonporous substrate.

Moreover, while some of the porous, column-filling media described in Swedberg are the same materials (*e.g.*, nylon and polymethylmethacrylate) as those that Swedberg describes as being useful for forming a substrate, Swedberg does not expressly or inherently describe applying a sample to a capillary column which includes a matrix formed from the *same material* as that of a nonporous substrate within which the capillary column is located.

1. Failure of Swedberg to Expressly Describe the Claimed Invention

In particular, Swedberg fails to mention that the same material may be used to form both a substrate and the porous medium with which columns in the substrate are filled. Swedberg also lacks any description of a miniaturized column device that includes a substrate with a column formed therein and a matrix within the column that are formed from the same material. The only express description of such a device is provided by in Example 1 of Swedberg, in which the miniaturized column device substrate is fabricated from the polyimide material KAPTON®. Swedberg, col. 33, lines 21-24. The exemplary miniaturized column device includes four sample treatment components. The first sample treatment component is filled with a matrix of a membrane material containing protein A/G, which binds to Immunoglobulins G, A, and M. Swedberg, col. 33, lines 29-34 & 58-61. The second sample treatment component contains an anti-convective media such as polyacrylamide, polymethylmethacrylate, or agarose. Swedberg, col. 34, lines 24-26. The third sample treatment component contains a liquid ampholyte or an ampholyte in a gel matrix. Swedberg, col. 34, lines 37-39. The fourth sample treatment component does not include a matrix. Instead, it is used for capillary zone electrophoresis to

effect a final separation function. Swedberg, col. 34, lines 56-61. None of the sample treatment components of the exemplary miniaturized column device described in Swedberg includes a matrix which is formed from the same material as the polyimide KAPTON® substrate. Accordingly, Swedberg fails to expressly describe application of a sample to a capillary column which includes a matrix that is formed from the same material as that from which a nonporous substrate in which the capillary column is located, as recited in independent claim 1.

2. Failure of Swedberg to Inherently Describe the Claimed Invention

Swedberg likewise fails to inherently describe applying a sample to "a porous capillary column comprising a matrix including the same material as said nonporous substrate . . ." It has been asserted that, because some of Swedberg's assortment of suitable substrates and column-filling matrices are the same (*i.e.*, nylon and polymethylmethacrylate), Swedberg "discloses that the porous matrix is formed in and from the same material as the nonporous substrate." Office Action dated May 16, 2002, page 5.

The Office has the burden of providing a basis in fact and/or technical reasoning to reasonably support the determination that the application of a sample to "a porous capillary column comprising a matrix including the same material as said nonporous substrate" necessarily flows from Swedberg's teachings. M.P.E.P. § 2112.

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993). As the Federal Circuit has articulated this principle more recently:

> To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'

In re Robertson, 169 F.3d 743, 745 (Fed. Cir. 1999) (citations omitted).

Applying this doctrine to the rejection of claim 1 under 35 U.S.C. § 102(b), the mere fact that the array of suitable substrates and column-filling matrices described in Swedberg ***could*** be combined in such a way as to produce a method which includes applying a sample to "a porous capillary column comprising a matrix including the same material as said nonporous substrate" is insufficient to establish anticipation.

Therefore, it cannot be said that Swedberg inherently describes use of capillary column that includes a matrix which is formed from the same material as the substrate in which the capillary column is formed.

Accordingly, it is respectfully submitted that, under 35 U.S.C. § 102(b), independent claim 1 is allowable over Swedberg.

Claims 2, 8, 12-17, and 30 are each allowable, among other reasons, as depending either directly or indirectly from claim 1, which is allowable.

Claims 18-29 and 31

Independent claim 18 of the above-referenced application is directed to a method which includes, among other things, applying a sample to a capillary column which is formed in a

nonporous substrate. The capillary column to which the sample is applied comprises a matrix that is formed from the same material as the nonporous substrate.

Again, for the same reasons provided herein with respect to independent claim 1, Swedberg does not expressly or inherently teach applying a sample to a capillary column which is formed in a nonporous substrate and which includes a matrix formed from the same material as that from which the nonporous substrate is formed.

Accordingly, it is respectfully submitted that Swedberg does not anticipate each and every element of independent claim 18.

Claims 19-29 and 31 are each allowable, among other reasons, as depending either directly or indirectly from claim 18, which is allowable.

In view of the foregoing, reversal of the 35 U.S.C. § 102(b) rejections of claims 1, 2, 8, and 12-31 is respectfully requested.

(9) APPENDICES

A copy of claims 1, 2, 8, and 12-31 as presently amended is appended hereto as "Appendix A."

(10) CONCLUSION

Appellant respectfully submits that claims 1, 2, 8, and 12-31 are allowable because Swedberg does not expressly or inherently describe each and every element of any of claims 1, 2, 8, or 12-31 of the above-referenced application.

Accordingly, reversal of the 35 U.S.C. § 102(b) rejections of claims 1, 2, 8, and 12-31 is respectfully solicited.

Respectfully submitted,

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APPENDIX A

1. A method of substantially isolating a constituent of a sample, comprising:

dispersing the sample in a mobile phase;

applying the sample to a first end of a porous capillary column formed in a nonporous substrate, said porous capillary column comprising a matrix including the same material as said nonporous substrate and at least one capture substrate disposed on said matrix; and

drawing the sample across a flowfront through said porous capillary column so as to enhance separation of the constituent from the sample by said at least one capture substrate.

2. The method of claim 1, further comprising detecting the constituent with at least one detector disposed proximate a detecting region of said capillary column.

8. The method of claim 1, wherein said dispersing comprises dissolving the sample in a liquid mobile phase.

12. The method of claim 1, wherein said applying comprises applying the sample to said porous capillary column with said at least one capture substrate comprising an antibody.

13. The method of claim 1, wherein said applying comprises applying the sample to said porous capillary column with said at least one capture substrate comprising an antigen.

14. The method of claim 1, further comprising applying a differential pressure to said capillary column to effect said drawing.

15. The method of claim 1, wherein said drawing occurs without applying differential pressure to said capillary column.

16. The method of claim 15, wherein said drawing comprises capillary action induced by said matrix.

17. The method of claim 1, wherein said drawing comprises applying an electrical current across a length of said capillary column.

18. A method of identifying the presence of a constituent in a sample, comprising:
providing the sample in a mobile phase;
applying the sample to a first end of a capillary column formed in a nonporous substrate, said capillary column comprising a matrix including the same material as said nonporous substrate;
drawing the sample across a flowfront through said capillary column and in contact with a stationary phase disposed at a selected location along said capillary column; and
detecting binding of the constituent with said stationary phase at said selected location.

19. The method of claim 18, wherein said detecting comprises applying a detection reagent to at least said selected location and analyzing said detection reagent to determine whether the constituent is present.

20. The method of claim 19, wherein said analyzing comprises quantifying a change in said detection reagent.

21. The method of claim 18, wherein said detecting comprises determining an electrical characteristic of said selected location and comparing said electrical characteristic to an electrical characteristic of a control.

22. The method of claim 18, further comprising applying said stationary phase to said matrix.

23. The method of claim 22, wherein said applying said stationary phase is effected before said applying the sample.

24. The method of claim 18, wherein said applying comprises applying the sample to said capillary column with said stationary phase comprising an antibody.

25. The method of claim 18, wherein said applying comprises applying the sample to said capillary column with said stationary phase comprising an antigen.

26. The method of claim 18, further comprising applying a differential pressure to said capillary column to effect said drawing.

27. The method of claim 18, wherein said drawing occurs without applying differential pressure to said capillary column.

28. The method of claim 27, wherein said drawing comprises capillary action induced by said matrix.

29. The method of claim 18, wherein said drawing comprises applying an electrical current across a length of said capillary column.

30. The method of claim 1, wherein said applying comprises applying the sample to said porous capillary column with said at least one capture substrate comprising at least one of an antibody and an antigen.

31. The method of claim 18, wherein said applying the sample comprises applying the sample to said capillary column with said stationary phase comprising at least one of an antibody and an antigen.